

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Altenschopfer et al.

Title: TRANSDERMAL
GRANISETRON

Appl. No.: 10/544,259

Filing Date: 12/9/2005

Examiner: Tran, Susan T.

Art Unit: 1618

Confirmation Number:
1348

**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. §1.705**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants respectfully request reconsideration of the Patent Term Adjustment (PTA) determined for the captioned patent application.

The Patent Office determined that the patent was entitled to 373 days of PTA. Applicants believe that this PTA determination was made in accordance with the "Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. §154(b)(2)(A)" published at 69 Fed. Reg. 34238 (Jun. 21, 2004). Under that interpretation of the PTA statute, any PTO delay under 35 U.S.C. § 154(b)(1)(A) is deemed to overlap with any 3-year maximum pendency delay under 35 U.S.C. § 154(b)(1)(B), and so, as a practical effect, PTA may be awarded under §154(b)(1)(A) or §154(b)(1)(B), but not both.

On September 30, 2008, the United States District Court for the District of Columbia issued a decision finding that the U.S. Patent and Trademark Office's interpretation of the PTA statute is incorrect. *Wyeth v. Dudas*, Civ. Action No. 07-1492 (JR) (Sep. 30, 2008). The court

determined that, under the correct interpretation of the PTA statute, periods of “overlap” are limited to “periods of time . . . [that] occur on the same day.” *Wyeth*, slip op. at 8. Thus, a PTO delay under §154(b)(1)(A) overlaps with a delay under §154(b)(1)(B) only if the delays “occur on the same day.” *Id.*

Applicants have recalculated PTA for the captioned application under the court’s interpretation of the PTA statute, and have determined that the patent is entitled to 466 days PTA, as shown on the attached sheet, which shows the relevant delays under 37 CFR §§1.702(a) and (b), and under 37 CFR §§1.703(a) and (b).

The attached sheet details the circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

| | |
|---|----------|
| (a) Total of non-overlapping PTO delay under §154(b)(1)(A) & (B): | 496 days |
| (b) Total Applicant delay: | 30 days |
| Final PTA Determination: | 466 days |

Applicants therefore respectfully request that the patent be accorded 466 days PTA.

The patent is not subject to a terminal disclaimer.

Payment of the requisite fee is submitted herewith. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

However, because this PTA error is due to a Patent Office error in interpreting and applying the PTA statute, a refund of the fee is respectfully requested.

Applicants request further that a decision on this request be **deferred or delayed** until a final decision has been rendered in *Wyeth v. Dudas*, which is now on appeal at the U.S. Court of Appeals for the Federal Circuit, under Federal Docket No. 2009-1120.

Respectfully submitted,

Date 7/14/09

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Patent Term Adjustment Calculation System

Docket Number: 041376-0801
 Application Number: 10/544259
 Patent Number: N/A

| | Event Description | Event Date | Days from Filing | PTO Days | Applicant Days |
|----------------|---|------------|------------------|----------|----------------|
| Edit Delete | Priority Date | 02/05/2003 | -912 | | |
| Edit Delete | International Filing Date | 02/05/2004 | -547 | | |
| | PCT National Stage Commencement Date | 08/05/2005 | 0 | | |
| Edit Delete | Notice to File Missing Parts | 11/21/2005 | 108 | | |
| Edit Delete | National Stage Entry (All 371(c) Requirements Met) | 12/09/2005 | 126 | | |
| Edit Delete | Response to Notice to File Missing Parts | 12/09/2005 | 126 | | |
| Edit Delete | Application Is Now Complete | 12/24/2005 | 141 | | |
| Edit Delete | IDS NOT failing under 1.704(c)(6), (8) or (10) filed at PTO | 04/07/2006 | 245 | | |
| Edit Delete | Preliminary Amendment under 1.704(c)(6) Received at PTO | 01/24/2007 | 537 | | |
| | 14 month From Application date | 02/09/2007 | 553 | | |
| Edit Delete | Non-Final Office Action | 03/18/2008 | 956 | 403 | |
| Edit Delete | Non-Final Office Action Rsp. Rcv'd at PTO | 04/02/2008 | 971 | | |
| Edit Delete | Final Office Action | 07/07/2008 | 1,067 | | |
| | 3 Year Period Starts | 08/05/2008 | 1,096 | | |
| Edit Delete | Advisory Action | 09/30/2008 | 1,152 | | |
| | Final Office Action + 3 months | 10/07/2008 | 1,159 | | |
| Edit Delete | Request For Continued Examination (including amendment) | 11/06/2008 | 1,189 | 93 | 30 |
| | 3 Year Period Stopped | 11/06/2008 | 1,189 | | |
| Edit Delete | Non-Final Office Action | 03/06/2009 | 1,309 | | |
| Edit Delete | Non-Final Office Action Rsp. Rcv'd at PTO | 03/20/2009 | 1,323 | | |
| Edit Delete | Notice of Allowance | 06/24/2009 | 1,419 | | |
| | Projected Patent Grant Date | 01/05/2010 | 1,614 | | |
| Totals: | | | | 496 | 30 |
| PTA: | | | | 466 | |

Created and maintained by
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